UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: GENZYME CORPORATION.	Civil Action No. 09-11267-GAO
JOHN RAHN, individually and on behalf of all others similarly situated, Plaintiff, v. GENZYME CORPORATION and HENRI A. TERMEER, Defendants.	
	CONSOLIDATED
VIVIAN OH, individually and on behalf of all others similarly situated, Plaintiff, v. GENZYME CORPORATION and HENRI A. TERMEER, Defendants.	Civil Action No. 09-11299-GAO

OPINION AND ORDER
March 30, 2012

O'TOOLE, D.J.

I. Introduction

The plaintiffs,[1] a class of investors, bring this securities fraud action against Genzyme Corporation and several individual executives of the company, Henri A. Termeer, David Meeker,

[1] On November 13, 2009, the Court appointed the group consisting of Deka International S.A. Luxembourg, the City of Edinburgh Council as Administering Authority of the Lothian Pension Fund, and the Government of Guam Retirement Fund (collectively the "Genzyme Institutional Investors") as Lead Plaintiff and consolidated Rahn v. Genzyme Corp., No. 09-11267-GAO, and Oh v. Genzyme Corp., No. 09-11299-GAO, into In re Genzyme Corp. Securities Litigation, No.

Alison Lawton, Mark R. Bamforth, Geoffrey McDonough, and Michael Wyzga ("Individual Defendants"). In Count I, the plaintiffs allege violations of Section 10(b) of the Securities Exchange Act (the "Exchange Act") and Rule 10b-5 against all defendants, and in Count II, violations of Section 20(a) of the Exchange Act against the Individual Defendants. Both Genzyme and the Individual Defendants have moved to dismiss the Consolidated Class Action Complaint.

II. Background

Genzyme is a leading international biotechnology company. Its products and services, sold in approximately 100 countries, are focused on diagnostic testing and on treating rare inherited disorders, kidney disease, orthopedics, and transplant and immune disease. This action was filed on July 29, 2009 on behalf of all individuals and entities who purchased Genzyme securities between October 24, 2007 and November 13, 2009 at prices the plaintiffs allege were artificially inflated by fraudulent statements and omissions by Genzyme and its six top executives, the Individual Defendants. The Consolidated Class Action Complaint alleges that the defendants failed to disclose material, adverse facts about U.S. Food and Drug Administration ("FDA") compliance issues and pervasive problems plaguing Genzyme's flagship plant in Allston, Massachusetts and other facilities, and repeatedly assured investors that the company was on track to receive FDA approval for a new product, Lumizyme, despite those problems. This purported failure to disclose material information allegedly caused the plaintiffs to suffer significant losses and damages.

09-11267-GAO. In re Genzyme Corp. Sec. Litig., No. 09-11267-GAO, slip op. at 1-2 (D. Mass. Nov. 13, 2009) (dkt. no. 30).

A. Company and Drug Overview

Genzyme's principal line of business is the production of drugs used to treat rare metabolic conditions associated with the absence of particular enzymes. Its three main products in this area, which generate about half of its annual sales, are: 1) Cerezyme, a treatment for Gaucher disease and Genzyme's top selling product; 2) Fabrazyme, a treatment for Fabry disease; and 3) Myozyme, a treatment for Pompe disease. These products are classified as "biologics" rather than "drugs" because they are composed of living biological organisms. Because of the living nature of the products, they are more susceptible to contamination than traditional drugs.

Genzyme began producing Myozyme in 2006 at facilities in Framingham and Allston, Massachusetts. In Framingham, Myozyme was produced in 160-liter ("160L") bioreactors, a production method approved for patients in the United States, and in Allston in 2000-liter ("2000L") bioreactors, approved only for use outside the United States. Because of the popularity of the product, Genzyme began to pursue production of Myozyme in larger quantities, including at the 4000L scale in its plant in Geel, Belgium[2] and at the 2000L scale in Allston for sale within the United States.

Genzyme sought FDA approval for 2000L Myozyme made at Allston to sell within the United States. In April 2008, the FDA determined that Myozyme produced at this scale should be addressed under a separate Biologics License Application ("BLA"), rather than simply through an amendment to the prior, existing approval for 160L Myozyme. Genzyme gave the 2000L scale a new name, Lumizyme, for the purposes of differentiation. The FDA advised

[2] Genzyme received approval from the European Medicines Agency to produce and sell Myozyme at the 4000L scale in February 2009.

Genzyme to expect a decision on the application in approximately seven months, or by November 29, 2008. This is known in FDA jargon as the "PDUFA date." [3]

B. Class Period Events

The Consolidated Class Action Complaint contains a large number of factual allegations set forth in 346 paragraphs spanning 135 pages. The following factual allegations, selected here for their pertinence to the ensuing discussion of the substance of the claims, are assumed to be true for purposes of evaluating the pending motions to dismiss. The summary includes information from documents cited in the Complaint, which is properly noticeable on consideration of the Rule 12(b)(6) motion.

1. The First Year

On October 24, 2007, the first day of the claimed class period, Henri A. Termeer, Genzyme's President, Chairman, and Chief Executive Officer, David Meeker, Executive Vice President, and Michael Wyzga, Chief Financial and Accounting Officer and Executive Vice President for Finance, participated in an investor conference call during which they assured investors that Genzyme's plan for FDA approval to manufacture Lumizyme—then still called Myozyme—in Allston was on track. Termeer stated that the picture was "very, very positive." (Consolidated Class Action Compl. ¶ 217 [hereinafter "Compl."].) Meeker agreed that approval was expected to come during the first quarter of the next year. Wyzga told investors that Cerezyme and Fabrazyme had contributed to top-line growth due to increases in patient accruals, and Termeer told analysts that he saw little threat from competitors because Genzyme did not foresee any reason patients would shift or change treatment.

[3] The PDUFA refers to the Prescription Drug User Fee Act of 1992, which requires the FDA to set goals for the length of time it will need to review an application. The "PDUFA date" is therefore the date by which the FDA has informed the applicant that it will try to reach a decision on the BLA.

Over the next year, the defendants continued similarly to assure investors. On its February 29, 2008 Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC"), for instance, Genzyme told investors that the Allston facility "contain[ed] extensive sterile filling capacity," (id. at ¶ 226), and in a Schedule 14A filed with the SEC on April 10, 2008, Genzyme asserted it was "positioned . . . well" for 2008 and was being "continually manage[d] . . . toward sustainable future growth," (id. at ¶ 228). The defendants also claimed fully to expect to receive FDA approval for Lumizyme in late 2008.

The plaintiffs allege that throughout this period and the time that followed, Genzyme was plagued by a host of pervasive and severe compliance deficiencies with respect to "current good manufacturing practices" ("CGMP"), see C.F.R. §§ 210, 211, particularly at its Allston plant, which were not adequately disclosed.

2. October 2008 Form 483 Letter and Viral Outbreaks at Geel and Allston

In September 2008, Genzyme's Geel plant, where 4000L Myozyme was manufactured for sale in Europe, experienced a bioreactor failure leading to rapid cell death. In November 2008, Genzyme's Allston plant experienced a similar bioreactor failure. Consequently, production at both Geel and Allston slowed considerably, decreasing the available supply of its biologics. Genzyme commenced an investigation, and it was later discovered that both contaminations were due to an outbreak of a rare virus strain known as Vesivirus 2117.

Additionally, in September and October 2008, the FDA inspected the Allston plant. The inspections identified at least sixteen deviations from CGMP, as reflected in a "Form 483" letter issued on October 10, 2008 ("October 2008 Form 483"). These "observations" from the inspection process detailed on the October 2008 Form 483 included:

- use of cryoshippers to ship raw material past their life expectancy and without required maintenance;
- failure to monitor amount of microbiological contamination on in-process material and chemical purification agents during purification;
- rouging on the chromatography columns, and lack of proper maintenance thereof;
- failure to properly test the heating, ventilation, and air-condition system;
- failure to properly monitor the composition of chemical agents used for purification;
- operation of fill lines at improperly high speeds, causing equipment malfunction; and
- inability to document whether numerous types of compliance actions had been taken.

Genzyme responded to the October 2008 Form 483 on October 31, 2008 with a proposed plan and timeline to address the problems, and supplemented the response in late February 2009.

With respect to the Lumizyme approval process, the same month that Genzyme received the October 2008 Form 483, an FDA advisory committee affirmed a study establishing the clinical effectiveness of Lumizyme produced at the 2000L scale.

During a conference call with investors on October 22, 2008 in which Termeer, Wyzga, Geoffrey McDonough, Genzyme's Senior Vice President, Alison Lawton, Genzyme's Senior Vice President of Global Product Access,[4] and Meeker participated, the defendants made no mention of the issues cited by the FDA's Form 483. When asked specifically whether anything was discussed at a closed manufacturing session that might affect the approvability of Lumizyme, no one mentioned the recent Form 483 or the Geel viral outbreak. McDonough shared the news of a FDA advisory panel's recent confirmation that Genzyme's study had demonstrated effectiveness of Lumizyme produced at the 2000L scale, and Lawton stated that clinical data was the most important piece of information at the time. McDonough reiterated that Genzyme expected action by November 29, 2008 (the "PDUFA date") and that "the likelihood of approval seems to be more certain, or at least is taking a more solid shape" than in the

[4] This appears to be Lawton's current position. According to the plaintiffs, Lawton has occupied various other positions at Genzyme and generally has been responsible for Genzyme's global regulatory activities across a broad range of products.

previous quarter. (Compl. ¶ 255.) During that same call, Termeer gave analysts a projected price per share in 2009 that included projected sales from the commercialization of Lumizyme in the United States and stated that Genzyme was in a "very robust position" to meet that figure. (Id. at ¶ 254.) A press release assured investors that Lumizyme was still on track for November approval.

In November 2008, the FDA informed Genzyme that certain aspects of the Lumizyme application were unexpectedly major amendments to the original Myozyme BLA, and therefore the time for FDA review would need to be extended. The FDA assigned Lumizyme a new PDUFA date of February 28, 2009. Genzyme disclosed this information to investors, adding that it did not expect the extension of FDA review to have any effect on its 2009 projections.

Over the next several months, through the end of February 2009, the defendants maintained that Lumizyme was on track for approval and that Genzyme was in a position to meet the growing demand for its other biologics, Cerezyme and Fabrazyme, which were also manufactured in Allston.

3. February 2009 Warning Letter

On Friday, February 27, 2009, Genzyme received a formal warning letter, addressed to Termeer, from the FDA regarding conditions at the Allston plant (the "Warning Letter"). In part, it stated:

> During the inspection the FDA investigators documented significant deviations from current good manufacturing practice (CGMP) in the manufacture of licensed therapeutic drug products, bulk drug substances, and drug components. These products include Fabrazyme, Cerezyme, and Myozyme. These deviations from GMP include non-compliance with section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (FD&C Act), the requirements of your biologics license application approved under 351 of the Public Health Service Act (PHS Act), and Title 21, Code of Federal Regulations (21 CFR) Parts 210 and 211.

> At the close of the inspection the investigators issued a form FDA 483, Inspectional Observations, which describe a number of significant objectionable conditions relating to your firm's compliance with CGMP . . . .

(Id. at ¶ 112.) The letter went on to repeat some of the same observations contained in the October 2008 Form 483 and criticized remedial plans that Genzyme had submitted to the FDA in response to the October 2008 Form 483. The FDA also warned Termeer that the various violations detailed in the Warning Letter constituted grounds to withhold the approval of any pending new drug applications.

That same day, Genzyme also received a Complete Response Letter from the FDA. The letter withheld approval of Lumizyme until certain items were addressed, including risk management and a post-approval verification study. The Complete Response Letter did not reference the Warning Letter, October 2008 Form 483, or Genzyme's responses to the October 2008 Form 483.

On Monday, March 2, 2009, Genzyme issued a press release disclosing receipt of the Warning Letter and summarizing its contents. It also disclosed that it had received the Complete Response Letter, which it described as "outlin[ing] the remaining items that had to be addressed before the [Lumizyme] could be approved." (Id. at ¶ 114.) The defendants also disclosed the receipt of the October 2008 Form 483.

That same afternoon, the defendants filed Genzyme's Form 10-K for the year ending December 31, 2008. The 10-K stated that approval of the pending Lumizyme was dependant on a satisfactory resolution of the problems raised in the Warning Letter and noted that the Warning Letter essentially identified and requested information regarding corrective actions involving the same problems that had been identified in the October 2008 Form 483. During a conference call

held the same day, Termeer stated that Lumizyme would not be approved by February 28, 2009, the then-existing PDUFA date.

The defendants continued to maintain that Genzyme was on track to cure the problems raised by the FDA within three to six months and that it was confident that the products produced in Allston continued to meet the highest quality and safety standards. Additionally, Mark Bamforth, Senior Vice President of Corporate Operations and Pharmaceuticals, denied that any of the problems highlighted in the Warning Letter would have an impact on Genzyme's manufacturing at Allston.

On March 24, 2009, Genzyme's Annual Report also contained reassurances to investors that Genzyme expected the Lumizyme BLA to be approved in mid-2009. On April 22, 2009, Lawton told investors that the Lumizyme BLA was "on schedule" for approval in the second or third quarter of 2009 and that Genzyme had resolved its outstanding issues with the FDA. (Id. at ¶ 134.)

On May 21, 2009, Genzyme issued a press release stating it had submitted final documentation to the FDA on issues regarding Lumizyme and that it still believed Lumizyme would be approved in 2009.

4. Another Viral Outbreak at Allston and Form 483

On June 16, 2009, about three weeks after the May release, Genzyme announced that it had detected a viral contamination outbreak at its Allston plant. It also disclosed for the first time the two earlier 2008 outbreaks. Each of the contaminations was disclosed as involving a rare virus strain, Vesivirus 2117. Because of the outbreak, Genzyme shut down the Allston facility for six to eight weeks. Lawton told investors that the most recent viral outbreak would not

require another inspection nor affect the Lumizyme BLA, and that Genzyme believed the BLA was still on track for approval in November 2009.

On July 27, 2009, the FDA informed Genzyme that it would reinspect the Allston facility. Genzyme announced the receipt of the letter through a press release on July 31, 2009.

On August 14, 2009, Termeer, Meeker, Lawton, and Bamforth wrote to the FDA to address the agency's concerns. The letter stated that Genzyme planned to make "fundamental systemic and cultural changes" as appropriate, and that Genzyme recognized that "the viral investigation and Allston . . . restart must be completed in the context of the broader compliance remediation activities." (Id. at ¶ 170.) The defendants continued to tell investors as late as November 2, 2009 that Lumizyme should be approved by late November.

On November 13, 2009, the last day of the claimed class period, the FDA issued Genzyme a second Form 483 ("November 2009 Form 483") and a Complete Response Letter, withholding Lumizyme approval. Among the observations detailed by the FDA, the November 2009 Form 483 noted that Genzyme had failed to implement various changes after it received the October 2008 Form 483. Additionally, that same day, Genzyme announced it had experienced another contamination at Allston. This contamination involved the discovery of foreign particles in drug vials.

5. Post-Class Statements

Several days later, Genzyme issued a press release formally announcing its receipt of the November 2009 Form 483 and Complete Response Letter. Genzyme told the market that it planned to address the deficiencies by "(a) establishing additional internal controls, (b) updating the Allston plant's fill/finish capabilities (*i.e.*, its capabilities for putting drugs into vials ('fill') and then sealing and labeling them ('finish')), (c) transferring additional filling activities to

existing Genzyme contract manufacturers, and (d) utilizing excess capacity at Genzyme's Waterford, Ireland facility." (Id. at ¶ 190.)

Genzyme hosted a conference call the same day. During the call, the defendants announced Genzyme would have to shut down Allston again temporarily in order to address the compliance issues. Termeer acknowledged that introducing the production of Lumizyme in Allston was a significant factor in the complications which had arisen and noted that Genzyme could explain how it came that it "overloaded the Allston facility with too much to do and then creating [sic] these difficulties." (Id. at ¶191.) Meeker stated that there were many issues of which they were aware and were working to address.

In December 2009, Termeer again discussed the problems of the overburdened Allston plant and noted that the "culture in the plant" needed to be changed. (Id. at ¶ 202.) He said that many of the functions performed at the Allston plant would be moving to other facilities, including moving the production of Myozyme.

On January 4, 2010, Genzyme issued a Form 8-K announcing that many of the functions previously performed at Allston would be moved to other facilities and to other contract manufacturers.

Finally, on May 24, 2010, the FDA filed a complaint in federal court to permanently enjoin Genzyme and Termeer from committing further violations of the Food, Drug, and Cosmetics Act. That same day, the parties entered into a consent decree requiring, among other things, Genzyme to pay a civil penalty of $175 million, to transfer fill/finish operations out of the Allston facility, and to implement a comprehensive remediation plan under the oversight of an independent expert approved by the FDA.

III. Discussion

A. Standard of Review

Under Federal Rule of Civil Procedure 12(b)(6), a defendant may move to dismiss an action against it for failure to state a claim upon which relief can be granted. In evaluating a motion to dismiss, a court must accept as true all well-pleaded facts and draw all reasonable inferences in the plaintiff's favor. Aldridge v. A.T. Cross Corp., 284 F.3d 72, 78 (1st Cir. 2002). However, the Court "need not credit a complaint's 'bald assertions' or legal conclusions." Glassman v. Computervision Corp., 90 F.3d 617, 628 (1st Cir. 1996) (internal quotations and citations omitted).

Furthermore, when deciding a motion to dismiss, a court "must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322-23 (2007).

B. Pleading Standard for Section 10(b) Fraud Claims

Counts I and II of the plaintiffs' complaint are brought under Sections 10(b) and 20(a) of the Exchange Act, as well as under Rule 10b-5 of the Rules and Regulations of the Exchange Act, 17 C.F.R. § 240.10b-5. Section 10(b) of the Exchange Act makes it unlawful in relevant part

> for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange—
>
> . . . .
>
> (b) To use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, or any securities-based swap agreement (as defined in section 206B of the Gramm-Leach-Bliley Act), any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as

> necessary or appropriate in the public interest or for the protection of investors.

15 U.S.C. § 78j(b).

SEC Rule 10b-5, promulgated under section 10(b), makes it unlawful:

> (a) To employ any device, scheme, or artifice to defraud,
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.

To state a claim for securities fraud under section 10(b) and Rule 10b-5, a plaintiff must allege: (1) a material misrepresentation or omission; (2) scienter, or a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation. In re Stone & Webster, Inc., Sec. Litig., 414 F.3d 187, 195 (1st Cir. 2005) (citing Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 341-42 (2005)).

Although Genzyme raised numerous arguments in its motion to dismiss, it notes—correctly—that the case most clearly turns on the second element, scienter. Scienter is a "mental state embracing intent to deceive, manipulate, or defraud." City of Dearborn Heights v. Waters Corp., 632 F.3d 751, 757 (1st Cir. 2011) (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976)). To satisfy the scienter element, a plaintiff must show that the defendant "engaged in 'intentional or willful conduct designed to deceive or defraud investors by controlling or artificially affecting the price of securities.'" Id. (quoting Hochfelder, 425 U.S. at 199.) Scienter can be demonstrated by establishing either that defendants "consciously intended to defraud, or that they acted with a high degree of recklessness." Aldridge, 284 F.3d at 82. A complaint may survive a motion to dismiss if it pleads "a highly unreasonable omission,

involving not merely simple, or even inexcusable, negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious the actor must have been aware of it." Id. (quoting Greebel v. FTP Software, Inc., 194 F.3d 185, 198 (1st Cir. 1999)).

Coupled with scienter, of course, is the related requirement that the misstatements or omissions must have been "material." An omission is material if there is a "substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." Basic, Inc. v. Levinon, 485 U.S. 224, 231-32 (1988) (citing TSC Industries, Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976)). See also Cooperman v. Individual, Inc., 171 F.3d 43, 49 (1st Cir. 1999). Not all adverse information must be disclosed; in fact, Rule 10b-5 does "not create an affirmative duty to disclose any and all material information." Matrixx Initiatives, Inc. v. Siracusano, --- U.S. ----, 131 S.Ct. 1309, 1321 (2011). Rule 10b-5 and §10b only require disclosure when necessary "to make…statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. §240.10b-5(b). See also, Matrixx, 131 S.Ct. at 1321. Additionally, if the materiality of a particular fact is in question, that "tends to undercut" an inference that a defendant acted with the requisite scienter. Waters, 632 F.3d at 757. See also MS Pub. Emp.'s Ret. Sys. v. Boston Scientific Corp., 523 F.3d 75, 78 (1st Cir. 2008) ("Knowingly omitting material information is probative, although not determinative, of scienter.")

In a securities case alleging fraud, the plaintiffs must additionally satisfy the heightened pleading standards of Federal Rule of Civil Procedure 9(b) and of the Private Securities Litigation Reform Act ("PSLRA"). Greebel, 194 F.3d at 193. The PSLRA requires in relevant part that a plaintiff "state with particularity facts giving rise to a strong inference that the

defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). The facts pled by the plaintiffs must make the inference "more than merely or plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of non-fraudulent intent." Id. (quoting Tellabs, 551 U.S. at 314)).

C. The Present Case

In making a determination regarding whether the plaintiffs have adequately pled scienter, a court must review "all the allegations holistically." Matrixx Initiatives, Inc. v. Siracuaso, --- U.S. ---, 131 S. Ct. 1309, 1324 (2011) (quoting Tellabs, 551 U.S. at 326). Here, the mammoth complaint contains a daunting number of allegedly fraudulent misrepresentations involving affirmative statements and omissions about a variety of events which the plaintiffs argue are related. The allegations appear to boil down, however, to essentially three threads: (1) bioreactor failures at the Geel and Allston facilities; (2) FDA inspections at the Allston facility; and (3) the Lumizyme approval process. Considering these threads separately not only helps sift through the morass of allegations, but also shows how, when considered collectively, they do not give rise to a compelling inference of scienter.

Bioreactor Failures: In late 2008, a year into what is alleged to be the class period, Genzyme suffered two bioreactor failures characterized by rapid cell death. The incidents were not publicly disclosed at the time. In mid-2009, another Allston bioreactor failed, and Genzyme disclosed all three failures, noting that they were caused by an outbreak of the rare Vesivirus 2117. No allegation is made, however, as to when the cause of the bioreactor failures was discovered by Genzyme.

FDA Inspections: One year into the class period and apparently unrelated to Genzyme's attempt to obtain FDA approval of Lumizyme, the FDA made observations of the Allston facility in its October 2008 Form 483, focusing generally on the fill-finish operations. Genzyme responded to the FDA that same month, but made no public disclosure. Later, apparently unsatisfied with Genzyme's response to the October 2008 Form 483, the FDA issued a Warning Letter regarding Genzyme's proposed corrective actions in February 2009, which Genzyme promptly disclosed and responded to. Several months later, the FDA told Genzyme it would reinspect the facility and Genzyme promptly disclosed that notification. Finally, in late 2009, the FDA issued its November 2009 Form 483, which Genzyme again promptly disclosed.

Lumizyme Approval Process: In the spring of 2008, Genzyme began seeking Lumizyme approval under its own BLA, and in October of that year, Genzyme made a major step towards obtaining FDA approval when an FDA advisory committee affirmed Genzyme's studies which had established the clinical effectiveness of the therapy. The next month, the FDA extended Lumizyme's PDUFA date to February 2009 because the application entailed unexpected amendments it considered major. In February 2009, the FDA issued a Complete Response Letter to Genzyme, which focused on risk management but made no reference to the Warning Letter issued that same month. Genzyme promptly disclosed receipt of the Complete Response Letter. In November 2009, the FDA issued a second Complete Response Letter, which Genzyme again promptly disclosed. In May 2009, Genzyme announced that the PDUFA date had been delayed until November 2009, and maintained this position up until early November 2009.

The plaintiffs take these three stories and interweave them with frequent allegations regarding knowledge, hoping perhaps in their cumulative form, as required by Tellabs, the allegations amount to an adequate allegation of scienter. Specifically, the plaintiffs claim that

the defendant's failure to disclose "gross departures" from CGMP and the subsequent impact on Lumizyme approval combined with "incomplete partial disclosures [and] fraudulent assurances" establish a compelling inference of scienter. (Pl.'s Mem. in Opp'n, 29 (dkt. 68).) What is missing, though, is any substantial link between the three factual threads. Instead of alleging specific connections between the various happenings, the plaintiffs rely only on general assertions that the defendants "knew" (or were reckless in not knowing) they were misleading investors by not saying more about some or all of the events. With respect to the element of scienter, however, "[t]he key question . . . is not whether the defendants had knowledge of certain undisclosed facts, but rather whether defendants knew or should have known that their failure to disclose those facts present[ed] a danger of misleading buyers to sellers." Waters, 632 F.3d at 758 (internal quotations and citations omitted). When this second question is addressed, the complaint's deficiencies become clear.

The claimed class period begins on October 24, 2007. The FDA did not issue any observations until October 2008, and the Geel and Allston contaminations also occurred in the fall of 2008. The plaintiffs do not explain how the defendants withheld information about these matters for a year before the events happened.

Furthermore, the inspectional observations by the FDA in October were of doubtful materiality. The very Form 483 itself includes statements that tend against a conclusion of materiality. The October 2008 Form 483 stated in bold, capitalized lettering that it was setting forth merely "INSPECTIONAL OBSERVATIONS" that "DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING . . . COMPLIANCE." (Decl. of Alison E.H. McLaughlin in Supp. of Def. Genzyme Corp.'s Mot. to Dismiss Consolidated Class Action Compl. Ex. A at 6 (dkt. no. 54-1).) The language was added to Form 483 by the FDA to

minimize any "perceived ambiguity [that might] result in inaccurate conclusions about the compliance of an inspected firm." Pub. Pension Fund Grp. v. KV Pharm. Co., 705 F. Supp. 2d 1088, 1100 (E.D. Mo. 2010) (citing FDA website). Because the Form 483 observations "do not represent a final agency determination," they are necessarily interim statements, subject to revision. They are meant to prod a company into taking corrective steps before any more substantial agency action is necessary. It simply cannot be that every critical comment by a regulatory agency – even about matters as important as good manufacturing practices -- has to be seen as material for securities law reporting purposes, especially in an industry like Genzyme's, where there is constant and close supervision by the FDA. See ACito v. IMCERA Group, Inc., 47 F.3d 47, 52-53 (2d Cir. 1995). Indeed, to think otherwise would be to insist on a flood of data that would overwhelm the market and would ironically be, in the end, actually uninformative.

The October 2008 Form 483 does not bolster any inference of scienter. Since, given the FDA's own view of the significance of the form, it is of questionable materiality in a securities law context, the complaint would have to be far more specific in its allegations about why the defendants' omissions to disclose it was done with the requisite intent to deceive. It is clear, based on the disclosures that were made, that this Form 483 would not impact any other statements disclosed, as contemplated by the 10b-5. 17 C.F.R. §240.10b-5(b). See also, Matrixx, 131 S.Ct. at 1321. Given the FDA's own warnings and enforcement policies surrounding its issuance, one can safely conclude that the immateriality the Form 483 negates any inference of scienter. See Waters, 632 F.3d at 757.

The fact that Genzyme eventually received the Warning Letter from the FDA does not change things. The receipt of the Warning Letter one and a half years into the class period does not establish Genzyme "knew" that it was out of compliance with CGMPs, or that the company,

through its directors, intended to deceive investors with respect to Lumizyme approval. First, even a warning letter from the FDA is "informal and advisory." In re Bos. Scientific Corp. Sec. Litig., 490 F. Supp. 2d 142, 161 & n.113 (D. Mass. 2007), *rev'd on other grounds*, Miss. Pub. Emps.' Retirement Sys. v. Bos. Scientific Corp., 523 F.3d 75 (1st Cir. 2008) (internal quotations omitted); see also Anderson v. Abbott Labs., 140 F. Supp. 2d 894, 902 (N.D. Ill. 2001) ("There is nothing magical about [an FDA] warning letter. Although the language sounds ominous, it really is rather boilerplate.") While it reflected the FDA's position on the matter, it did not commit the FDA to taking enforcement action. In any event, the Warning Letter was promptly disclosed to the market. Furthermore, the Complete Response Letter from the FDA with respect to its Lumizyme approval process that was received around the same time as the Warning Letter did not make any link or connection with the issues mentioned in the Warning Letter or the October 2008 Form 483 or Genzyme's responses (adequate or otherwise) to the October 2008 Form 483. Rather than focusing on fill/finish operations, as those other FDA communications had, the Complete Response Letter appears to have focused in large part on Genzyme's submission of a risk evaluation and mitigation strategy required by the Food, Drug, and Cosmetic Act. In other words, it did not raise the significance of the other communications on other issues.

The plaintiffs also argue that it "knew" Genzyme's Allston facility was "severely overburdened," which created a risk that it would be unable to adequately supply the Lumizyme market. Specifically, the plaintiffs complain of the bioreactor failures at the Genzyme facilities and suggest broadly that the viral contaminations should be considered in concert with the October 2008 Form 483. But the complaint does not allege a particularized link between the bioreactor failures and the observations noted on the October 2008 Form 483. Furthermore, by

the plaintiffs' own allegations, the bioreactor failures were caused by an outbreak of Vesivirus 2117, an "extremely rare" virus. (Compl. ¶ 95.) Tellingly, the plaintiffs do not allege when Genzyme was aware that the rapid cell death, potentially attributable to many different causes, was in fact caused by an extremely rare (and thus, likely unforeseen) viral outbreak.

The plaintiffs further allege that Genzyme's directors "knew" that the concerns raised by the FDA would not be timely resolved by Genzyme's proposed corrective measures. But again the plaintiffs fail to identify specific facts to support the requisite inference. They point to the fact that the FDA later concluded Genzyme did not adequately implement its corrective plans. However, the fact that the FDA later made such a conclusion does not make earlier statements about the Lumizyme approval process false or misleading. The allegations in this respect amount to fraud by hindsight, asking the Court to "'essentially infer[] earlier knowledge based only on the situation that later came to pass,' which the First Circuit has 'consistently rejected.'" See In re The First Marblehead Corp. Sec. Litig., 639 F. Supp. 2d 145, 160 (D. Mass. 2009) (quoting Rodríguez-Ortiz v. Mango Caribe, Inc., 490 F.3d 92, 97 (1st Cir. 2007)). A "plaintiff may not simply contrast a defendant's past optimism with less favorable actual results, and then contend[] that the difference must be attributable to fraud." Miss. Pub. Emps.' Ret. Sys., 523 F.3d at 90 (internal quotations omitted).

The plaintiffs also refer to comments made by Individual Defendants regarding certain "systemic and cultural changes" it needed to make at the facility-level. That management eventually became aware of certain problems, including potentially overburdening a particular plant, does not necessarily mean that the directors knew or were reckless in not knowing along the way that their statements regarding the approval process would be misleading. The knowledge—gleaned at some point by certain individuals—is insufficient to indicate the

requisite mental state "embracing intent to deceive, manipulate, or defraud" at the time the purported omissions or partial disclosures occurred. See Hochfelder, 425 U.S. at 193 n.12.

Taken collectively, the allegations do not give rise to a cogent and compelling inference that the defendants withheld disclosure of the disputed information *not* because they believed the information to be unimportant or its disclosure unnecessary, but because they understood – and sought to prevent -- its likely informative effect on the market. To be sure, the plaintiffs' theory is plausible, and perhaps even reasonable. But plausibility and reasonableness are insufficient to support a strong inference of fraudulent intent. See Tellabs, 551 U.S. at 314.

Instead, the inference of a nonculpable explanation for the defendants' actions— is stronger than the one the plaintiffs implore the Court to draw. That is, more compelling instead is the inference that Genzyme was attempting to develop a biologic that the defendants considered to be beneficial and that they believed was progressing, if fitfully at times, towards FDA approval for Lumizyne, and that they reasonably did not expect that the setbacks the company experienced in various ways would have a significant impact on the ultimate approval so as to require more disclosure than there had been. See Waters, 632 F.3d at 759.

And, of course, there had been considerable disclosure of adverse information. Much information of the kind the plaintiffs contend was concealed was in fact made public, and promptly so. The record clearly establishes Genzyme's repeated and timely disclosures of those facts material to investors. The disclosure of the February 2009 Warning Letter, the July 2009 FDA letter, the November 2009 Form 483, the February 2009 Complete Response Letter, the November 2009 Complete Response Letter, and the May 2009 delay of the FDUFA date all establish Genzyme's transparency throughout the class period. These repeated and timely

disclosures of material information seriously undermine an inference of intent to deceive. See Horizon Asset Mgmt., Inc. v. H&R Block, Inc., 580 F.3d 755, 763-64 (8th Cir. 2009).

Additionally, there were many indications that Lumizyme approval would be forthcoming. In October 2008, a year into the class period, an advisory committee of the FDA voted to affirm a study that established the clinical effectiveness of Lumizyme. Clinical effectiveness is a key element in the FDA approval process, and the company appropriately viewed the vote as a sign it was moving in the right direction. Furthermore, in February 2009, Genzyme received approval by the European Medicines Agency to produce and sell 4000L Myozyme, which was also produced at the Allston facility. That approval tended to lend support to a legitimate belief that the FDA application would be similarly approved. See In re AstraZeneca Sec. Litig., 559 F. Supp. 2d 453, 471 (S.D.N.Y. 2008) (finding that facts such as the approval of drug in Europe "made it not unreasonable for defendants to believe in their product" and weighed against finding of scienter); Oppenheim Pramerica Asset Mgmt. S.A.R.L. v. Enxysive Pharm., Inc., No. H-06-3022, 2007 WL 2720074, at *4 (S.D. Tex. Sept. 18, 2007) (finding no scienter when, among other things, defendant's approval in Europe, Canada, and Australia lent support to defendant company's belief of FDA approval).

In sum, the plaintiffs' assertions, while numerous, are too speculative to give rise to a strong inference of scienter. That Genzyme encountered FDA compliance issues, while perhaps the appropriate subject matter of FDA enforcement action, is insufficient in light of all the circumstances to impute the requisite culpable state of mind to the company and its leaders.

The complaint fails adequately to allege the essential element of scienter and consequently, it must be dismissed.

D. Claims against Individual Defendants

Section 20(a) provides for derivative liability for persons who "control" others who are primarily liable under the Exchange Act. Greebel, 194 F.3d at 207. Where, as here, the complaint fails to allege an underlying violation of the securities laws, the Section 20(a) claims must also be dismissed. Id.

III. Conclusion

For the foregoing reasons, the defendants' motions to dismiss (dkt. nos. 62 & 65) are GRANTED. The clerk shall enter a judgment dismissing the consolidated cases.

It is SO ORDERED.

/s/ George A. O'Toole, Jr.
United States District Judge